

USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also MPEP 2143.01.

In this case, the prior art could not be modified so as to result in the combination defined by the claims at issue, as such prior art would not have made the modification obvious. In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986). Recognizing, after the fact, that such a modification would provide an improvement or advantage, without suggestion thereof by the prior art, rather than dictating a conclusion of obviousness, is an indication of improper application of hindsight considerations. Simplicity and hindsight are not proper criteria for resolving obviousness. See, In re Warner, 379 F.2d 1011, 154, USPQ 173 (CCPA 1967).

Turning first to the primary references, and assuming *arguendo* that other claim elements are disclosed, Lai U.S. Patent No. 5,034,461 (" '461 Patent) 5,760,100, Lai U.S. Patent 5,158,717 (" '717 Patent) , U.S. Patent No. 5,219,965 (" '965 Patent") and U.S. Patent No. 5,334,681 (" '965 Patent) to Mueller et al all fail to describe any any effective surface treatment. Turning now to the secondary references, each of the references lacks sufficient motivation to one of ordinary skill in the art to conduct the surface treatment, as presently claimed. U.S. Patent No. 4,214,014 (" '014 Patent) to Hofer et al. describes surface modification for contact lenses, which uses a setup that actually sputters the surface of the contact lens away, cleaning the surface and oxidizing it. U.S. Patent No. 4,687,816 (" '816 Patent) discloses a treatment of a specific type of soft lens with a very specific acid anhydride while the lens is swollen, which cannot be fairly be extended to other type of lens. U.S. Patent No. 4,980,208 (" '208") describes a methodology for use with hard lenses, not silicone hydrogel lenses. U. S. Patent No. 5,391,589 (" '589 Patent) discloses grafting surfaces onto lenses; and specifically hard lenses, which is inapplicable to the present invention.

Based upon the description of the above secondary references, each of the references is very specific to a specific material, and one of ordinary skill in the art would not be motivated to use such techniques for surface treatment of the present invention. Clearly, there is no motivation in the secondary references that it would be desirable for

one of ordinary skill in the art to improve any lens of the primary references by the surface treatment methods of Hofer, Lin, Sugiyama, or Kiguchi.

**II. For Clarity and in Order to Claim the Full Scope of Applicants Invention, The Above Claims Have Been Amended**

For clarity, a Applicant's have amended the above claims to correct minor typographical corrections, and for further clarity of expression of the scope of the invention. The specific changes are set forth in the Appendix attached to this supplemental response.

The Applicants have also changed claims 207 and 217 to reflect the sterilization of the lenses, which to one of skill in the art may be carried out by autoclaving or other sterilization techniques. See, e.g., Example B5 at pages 69-70 where autoclaving of lens is described, and Websters New World Dictionary, Third College Edition (1988) describes "autoclaving" as "to sterilize."

### **III. Request for Reconsideration and A Notice of Allowance.**

For the above reasons, Applicants request reconsideration of the above rejections, and issuance of a Notice of Allowance. To the extent a further interview will clarify any issues now before the Examiner, the Applicant will be pleased to confer with the Examiner.

Respectfully submitted,

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## **APPENDIX**

### **MARK UP OF AMENDMENTS TO SPECIFICATION AND CLAIMS**

#### **IN THE SPECIFICATION:**

Please replace the paragraph beginning at Page 1, line 3 and ending at line 5 of the patent specification with the following replacement paragraph.

This application is a continuation of Serial No. 09/262,542, filed on March 4, 1999, which is a continuation of Serial No. 09/108,714, filed July 1, 1998, which is a divisional of application Ser. No. 08/682,452, filed July 16, 1996, which is a divisional of application Ser. No. 08/569,816, filed December 8, 1995, which is a continuation-in-part of U.S. Application No. 08/301,166, filed on September 6, 1994. Priority is also claimed under 35 U.S.C. §119 for German Application No. 95810221.2 filed on April 4, 1995 and Swiss Application No. 1496/95 filed on May 19, 1995.

#### **IN THE CLAIMS:**

A mark up of the amendment of the above claims is presented below:

187. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material formed from [comprising] a silicone copolymer which provides a high ion permeability and a high oxygen permeability; said silicone copolymer comprising an oxyperm polymerizable material, and an ionperm polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and

irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

188. (Amended). The extended contact lens of claim 187 wherein said core polymeric material formed from [comprises a fluorine macromer, and] N-vinyl pyrrolidone.

192. (Amended). A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material being [having] formed from polymerizable materials comprising:

- (a) an oxyperm polymerizable material, [,] and
- (b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about  $6.4 \times 10^{-6} \text{ mm}^2/\text{sec}$  or an Ionoton Ion Permeability Coefficient of greater than about  $0.4 \times 10^{-6} \text{ cm}^2/\text{min}$ ,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

193. (Amended). The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from [comprises a fluorine containing macromer as said oxyperm material and] N-vinyl pyrrolidone as said ionoperm material.

205. (Amended). The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep [steep] periods, less than about 8% corneal swelling.

207. (Amended). A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

- (a) forming a pre-polymer [polymeric] core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components [lens] formulation;
  - (b) polymerizing the core in an atmosphere substantially free from oxygen;
  - (c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and
  - (d) autoclaving lens at predetermined temperatures;
- whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and
- whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,
- wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without

having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$  or (2) by an Ionoflux Ion Permeability Coefficient of greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ , wherein said ion permeability is measured with respect to sodium ions.

217. (Amended). The lens of claim 212, including © said lens being sterilized [at predetermined temperatures].

218. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

- a) preparing a lens formulation comprising an oxypem polymerizable material, and an ionopem polymerizable material, wherein said oxypem polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;
- b) placing said lens formulation in a lens mold;
- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxypem polymerizable material and said ionopem polymerizable material of said lens formulation form separate oxypem and ionopem phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and

- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

219. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

- a) preparing a lens formulation comprising an oxypm polymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing monomers and fluorine-containing monomers, and an ionopm polymerizable material, wherein said oxypm polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;
- b) placing said lens formulation in a lens mold;
- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxypm polymerizable material and said ionopm polymerizable material of said lens formulation form separate oxypm and ionopm phases; said lens core material having at least one continuous pathway from said inner surface to said outer surface for oxygen transmission therethrough;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and
- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens[.];

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

223. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine- containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least one continuous pathway from said upper surface to said lower surface for oxygen treatment; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

224. (Amended). The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising [comprises] a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

228. (Amended). A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material [having] formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater [grater] than about  $6.4 \times 10^{-6}$  mm<sup>2</sup>/sec or an Ionoton Ion Permeability Coefficient of greater than about  $0.4 \times 10^{-6}$  cm<sup>2</sup>/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

234. (Amended). The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers [days].